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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/597,584	07/31/2006	Roy Harris	82029-2	3178

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EXAMINER	
ORWIG, KEVIN S	

ART UNIT	PAPER NUMBER
1611	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/597,584	HARRIS ET AL.	
	Examiner	Art Unit	
	Kevin S. Orwig	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *Oct. 10, 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *64-74* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *64-74* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *Jul. 31, 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

Claims 64-74 are currently pending and are the subject of this Office Action. This is the first Office Action on the merits of the claims.

Election/Restrictions

Applicants' election of Group I (claims 64-74) in the reply filed on Oct. 10, 2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 1-63 and 75-97 have been cancelled.

Priority

The earliest effective U.S. filing date afforded the instantly claimed invention has been determined to be Feb. 17, 2005, the filing date of PCT application PCT/GB/05/000566 to which the instant national stage 371 application claims priority.

Acknowledgment is made of applicant's claim to foreign priority under 35 U.S.C. 119(a)-(d). The certified copy of the British application was filed with the USPTO on Jul. 31, 2006.

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. In order to receive the benefit of an earlier filing date under 35 U.S.C. 120, the later-filed application must be an application for a patent for an invention which is also disclosed in the prior application

(the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosures of prior-filed PCT/GB05/000566 and British application No. 0403406.2 (filed Feb. 17, 2004) fail to provide adequate written support in the manner provided by the first paragraph of 35 U.S.C. 112 for claims 64-74 of the instant application. Instant claim 64 recites "...activated derivative thereof". This recitation is not properly supported as set forth in the written description rejection below. Thus, claims 64-74 are afforded a date of Sep. 19, 2006, the filing date of the instant application.

Claim Rejections - 35 USC § 112 (1st Paragraph)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Written Description

Claims 64-74 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed,

had possession of the claimed invention. Specifically, claim 64 recites an alkylene dicarboxylic acid spacer or an activated "derivative thereof".

Regarding the requirement for adequate written description of chemical entities, Applicant's attention is directed to the MPEP §2163. In particular, *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1568 (Fed. Cir. 1997), *cert. denied*, 523 U.S. 1089, 118 S. Ct. 1548 (1998), holds that an adequate written description requires a precise definition, such as by structure, formula, chemical name, or physical properties, "not a mere wish or plan for obtaining the claimed chemical invention." *Eli Lilly*, 119 F.3d at 1566. The written description requirement can be met by "showing that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics," including, *inter alia*, "functional characteristics when coupled with a known or disclosed correlation between function and structure..." *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 296 F.3d 316, 1324-25 (Fed. Cir. 2002) (quoting Guidelines, 66 Fed. Reg. at 1106). See MPEP § 2163.

There are two issues related to the written description issue. First, in paragraphs [0044]-[0045] of the specification, applicants mention that it is desirable for the space to be activated, i.e. for the functional groups of the spacer to be converted to groups of greater reactivity towards groups in the protein. Applicants discuss only one class of activators (i.e. carbodiimide compounds) and specifically exemplify only ethyl[dimethylaminopropyl]-carbodiimide (EDC) for use as the dicarboxylic acid activator. No mention is made of other classes of compounds that the ordinary artisan would know to be used as activators, for example, symmetrical or mixed anhydrides,

acyl chlorides, or azides. Thus, it is not clear that all possible activators encompassed by the claim were envisioned as part of the invention.

Second, applicants have failed to provide any further description of the various derivatives as recited in instant claim 64 that would provide adequate written description of the compounds encompassed by the claim. Adequate written description requires a precise definition, such as by structure, formula, chemical name, or physical properties. Applicants provide no direction as to what subset of derivatives out of all possible derivatives that exist in the art would possess the required properties and be useful as an appropriate spacer compound. An ordinary artisan would recognize that, *inter alia*, polymers and degradation products of the dicarboxylic acids claimed would be encompassed by the genus of "derivative." These compounds include those that do not conform to the formula in claim 64. Furthermore, no derivatives were disclosed in the specification are to provide guidance to the artisan.

Additionally, the ambiguity of the term "activated" as discussed above exacerbates the written description issue. In the present case, other than the specific compounds mentioned, the disclosure fails to describe the claimed compounds in a manner that complies with the written description requirement of 35 U.S.C. 112, 1st Paragraph. While the specification provides the structures of compounds conforming to the formula of claim 64, e.g. adipic acid and glutaric acid activated with EDC, no derivatives are described. Thus the specification is insufficient to convey possession of the entire genus encompassed by the claimed "derivative[s]". The skilled artisan would have been unable to readily envision the chemical structures of the claimed subject

matter. As such, the instant claims lack adequate written description of "derivative[s]" as recited in claim 64.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 64, 66, 72, and 73 are rejected under 35 U.S.C. 102(b) as being anticipated by GAGNIEU (U.S. 5,412,076; Issued May 2, 1995).

1. Gagnieu discloses a crosslinked collagen material and process of its manufacture for use in implants or medical articles, and specifically teaches that the materials are useful as dressings and surgical glues (abstract; column 11, lines 18-19 and 38-39). Gagnieu teaches forming a collagen (i.e. protein) polymer by reacting collagen with a dicarboxylic acid spacer compound (abstract; column 2, lines 26-30 and 38; column 5, lines 16-27 and 37-40; column 7, lines 14-21). Glutaric acid, which is encompassed by the formula recited in claim 64 (i.e. n = 3 for glutaric acid) is mentioned as a preferred dicarboxylic acid spacer compound (column 7, lines 22-33; claims 4, and 13). Gagnieu teaches activation of the carboxyl groups of the spacer subunit with carbodiimide compounds (column 6, lines 38-45; column 8, lines 4-12). Thus, Gagnieu anticipates claims 64, 66, 72, and 73.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 64, 65, 69-71, and 74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gagnieu in view of WILKIE (U.S. 2002/0022588; Published Feb. 21, 2002).

2. The teachings of Gagnieu are presented above. Gagnieu does not teach forming the protein polymer *in situ,* does not teach using a recombinant protein source, and does not teach the use of proteins other than collagen.

3. However, Wilkie discloses protein-based implants and surgical sealants and methods of making them (abstract). The materials taught by Wilkie comprise crosslinked proteins, preferably human albumin (paragraphs [0012], [0030], and [0038]; claims 3 and 5). These proteins may be natural or synthetic, such as those that are recombinantly produced (paragraph [0030]). Wilkie teaches a method of forming a polymeric protein tissue sealant (i.e. a wound dressing) comprising the steps of providing a protein solution and reacting the protein with a crosslinker (claims 1 and 2). In one embodiment, the solution is allowed to crosslink after application to the wound tissue (i.e. the protein polymer is formed *in situ*) (claim 2). Wilkie teaches that the albumin may be derivatized with, *inter alia*, dicarboxylic acids such as glutaric anhydride (the anhydride form of glutaric acid) (paragraphs [0042] and [0246]). Additionally, Wilkie that the proteins can be crosslinked with any crosslinking agent known in the art and teaches EDC as a preferred crosslinking agent (paragraphs [0013], [0048]-[0052] and [0062]).

4. In light of these teachings, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to substitute albumin, specifically

human serum albumin, for collagen in the method and composition of Gagnieu. One would have been motivated to do so since Wilkie teaches that both collagen and albumin are preferred proteins for use in the invention. Gagnieu teaches the use of collagen, and the prior art establishes that albumin and collagen are functionally equivalent (per the teachings of Wilkie) in this type of crosslinked protein wound dressing (paragraphs [0012], [0030], and [0038]; claim 3). Thus, it would be obvious to the skilled artisan to substitute one functionally equivalent protein for another, and the combination of Gagnieu and Wilkie renders claims 65, 69-71, and 74 obvious.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, in the absence of evidence to the contrary, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

Claims 64, 67, and 68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gagnieu in view of Wilkie and further in view of PATHAK (U.S. 2004/0002456; Published Jan. 1, 2004).

5. The teachings of Gagnieu and Wilkie are presented above. Neither Gagnieu nor Wilkie teaches incorporating a supporting substrate or a vapor-permeable membrane into the dressing.

6. However, Pathak discloses methods of making crosslinked albumin hydrogels for use in wound dressings (abstract; paragraph [0060]). Pathak further teaches that the polymeric wound dressing composites can be produced in various shapes and sizes, and can be produced as laminates (paragraph [0068]) and can be reinforced with various flexible or rigid fibers and meshes (paragraph [0069]). Pathak teaches that the insertion of fibers or fibrous structures (i.e. a supporting substrate) improves the flexibility and tear resistance of the dressings (paragraph [0069]). Furthermore, Pathak teaches that flexible plastic film, which is permeable to oxygen, such as polyethylene may be applied on top of the wound dressing to prevent moisture loss.

7. In light of these teachings, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to incorporate a supporting substrate and a vapor-permeable membrane into the wound dressing compositions of Gagnieu. One would be motivated to do so to produce a wound dressing with increased flexibility and tear resistance and with improved moisture retention as taught by Pathak. One would have had a high expectation of success in doing so since Gagnieu, Wilkie, and Pathak all seek to address a similar issue, the production of improved biocompatible wound dressings. Thus, it would be obvious to the skilled artisan to include dressing structures that were known in the prior art to improve substantially similar dressing

compositions, and the combination of Gagnieu, Wilkie, and Pathak renders claims 67 and 68 obvious.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, in the absence of evidence to the contrary, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

Conclusion

No claims are currently allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin S. Orwig whose telephone number is (571)270-5869. The examiner can normally be reached Monday-Friday 7:00 am-4:00 pm (with alternate Fridays off). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached Monday-Friday 8:00 am-5:00 pm at (571)272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KSO

/David J Blanchard/
Primary Examiner, Art Unit 1643